

**REMARKS**

The Applicants thank the Examiner for the thorough consideration given the present application. Claims 11-14 are pending. Claims 1-10 were previously canceled. Claim 11 is independent and is amended herein. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

**Reasons for Entry of Amendments**

At the outset, it is respectfully requested that this Amendment be entered into the Official File in view of the fact that the amendments to the claims automatically place the application in condition for allowance.

In the alternative, if the Examiner does not agree that this application is in condition for allowance, it is respectfully requested that this Amendment be entered for the purpose of appeal. This Amendment was not presented at an earlier date in view of the fact that Applicants did not fully appreciate the Examiner's position until the Final Office Action was reviewed.

**Acknowledgement of Information Disclosure Statement**

It is gratefully appreciated that the Examiner has acknowledged the Information Disclosure Statement filed on January 30, 2002, as well as the Information Disclosure Statement filed on July 25, 2002.

**Rejection Under 35 U.S.C. §103(a)**

Claims 1-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Anhauser et al. (U.S. 5,115,913) in view of WO 96/34633. This rejection is respectfully traversed.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, independent claim 11 is amended herein to recite a combination of method steps in a method of preventing pressure-sensitive adhesive from leaking out in cold-flow during prolonged storage of a pressure-sensitive adhesive substrate section which is sealed in a bag in order to be protected against loss of active substance, said substrate section comprising:

A method of preventing pressure-sensitive adhesive from leaking out in cold-flow during prolonged storage of a pressure-sensitive adhesive substrate section which is sealed in a bag in order to be protected against loss of active substance, said substrate section comprising:

a backing layer; and

a matrix connected to said backing layer, the matrix either being comprised entirely of a pressure sensitive adhesive material or provided with a pressure-sensitive adhesive layer on an application surface thereof;

a detachable carrier layer which covers said pressure-sensitive adhesive material or layer, and which projects at least partially beyond said substrate sections and which is divided by an incision into two sections;

said method comprising:

configuring said two carrier layer sections, the two carrier layer sections projecting at least partially beyond said matrix, and overlapping each other in a region where they are joined, said overlap being positioned on said pressure-sensitive adhesive substrate material or layer.

The Applicants respectfully submit that the combination of method steps set forth in independent claim 11, as amended herein, is not disclosed or made obvious by the prior art of record, including Anhauser et al. and WO '633.

Independent claim 11 is amended by adding the description of the "carrier layer"; this layer belongs to the "substrate section" mentioned in the first paragraph of the claim, and it is divided by an incision into two sections. This amendment is based on claim 1 as originally filed (see also page 1 of the description, first paragraph). Furthermore, the carrier layer is characterized as a "detachable" carrier layer (see original description, page 3, first paragraph, line 6). In the last paragraph of the claim, the term "substrate section" is replaced by "substrate material or layer", to make it clear that the carrier layer is placed on top of an adhesive surface (see description page 3, lower half; referring to Figure 1). Since these features were already

present in original claim 1, re-introducing these features should be allowable. Due to the addition of the new paragraph describing the “detachable carrier layer”, it appears that reciting the step of “providing a carrier layer...” would be redundant; therefore this step has been deleted from claim 11.

These amendments are to set forth a condition of elements wherein substrate sections are covered by a backing layer on one side, and by a carrier layer on the other side, and that this carrier layer is divided by an incision.

As with regard to non-obviousness, the Applicants present the following arguments: The Examiner’s line of reasoning relies on USP ‘913 as a starting point which the skilled person would have chosen to tackle the problems that were solved by the present invention. However, it is made clear by the present description, and by the wording of claim 11 as well, that the present invention concerns substrate sections having a pressure-sensitive adhesive layer which is covered on one side by a backing layer, and on the other side by a carrier layer, which carrier layer is divided by an incision to form a detachment aid.

By contrast, the USP ‘913 relates to substrate sections, which are not covered by a detachable carrier layer that is divided by an incision (see Figures 1-6; column 2, lines 28-32).

Therefore, it does not appear appropriate to select USP ‘913 as a starting point for the evaluation of non-obviousness in the present case.

On page 3, lines 4-5, of the Office Action, it was stated that “the difference between the present invention and the cited reference (USP ‘913) is the structure of the carrier layer that prevents the migration of the PSA”. This statement, however is no longer applicable as USP ‘913 does not disclose the presence of a detachable carrier layer which is divided by an incision, as required by present claim 1.

The problem addressed by the present invention concerns the suppression of leakage (caused by cold flow) in cases where a detachable carrier layers is used which has an incision (see present description, page 1, first paragraph). The “carrier layer” mentioned in USP ‘913 is continuous and does not have an incision; therefore, there is no risk of adhesive leaking out through incision (see present description, page 1, first paragraph). In contrast, USP ‘913 is concerned with adhesive escaping around the substrate sections (column 1, lines 26-30). Clearly, leakage of adhesive through an incision present in a detachable carrier layer constitutes a different problem as compared to leakage of adhesive which occurs in the periphery of a substrate section.

Therefore, the skilled person trying to improve the storage properties of substrate sections as defined in present claim 11 would not have turned to USP ‘913 to solve this problem.

As pointed out in the last response, the teaching of USP '913 aims at preventing adhesive from sticking to the packing after the adhesive has already escaped, whereas the present invention aims at preventing the adhesive from escaping from the substrate section.

The object of the invention of USP '913 was to prevent agglutination of the supporting layer with the packing layer after adhesive has already escaped around the substrate sections.

On the other hand, the object of the present invention was to prevent leakage of adhesive leakage (in the region of incision), so that agglutination with the packing would not occur.

In conclusion, since USP '913 does not pertain to substrate sections that are covered by a carrier layer having an incision, and since this prior art document aims at a different problem, we take the position that this document is not suitable as a starting point for assessing the patentability of the instantly claimed invention.

WO '633 does not address the problem of leakage of adhesive caused by cold flow. This document discusses only the possible leakage of active compound in or through the backing material (page 1, fourth paragraph, first sentence; page 2, last paragraph). Since the active substance-containing reservoir is in direct contact with the backing material, leakage of the active compound through the backing material occurs with any type of reservoir material (compress, swab, matrix; page 1, second paragraph) and is unrelated to the "cold flow"-induced creeping of adhesive material mentioned in the present application.

On page 1, last paragraph, of WO '633, the possible disadvantageous consequences of leakage of active substance through the backing material are discussed. These disadvantages are only linked to the loss of active substance. None of these various disadvantages concerns the problem solved by the present invention, i.e. the risk of substrate sections sticking to the inside of the packing due to leakage of adhesive (see present specification, page 1, last 2 lines, to page 2, first paragraph). Also, there is not any passage in WO '633 which might suggest that the invention described in this document has anything to do with the problem of preventing the leakage of adhesive or, in particular, leakage of adhesive caused by cold flow.

In accordance with the above, it should be noted that the "compress, swab, matrix or similar reservoir" mentioned in WO '633 (page 2, third paragraph (II)) is not described as being adhesive or containing an adhesive layer. Only the backing layer is described as being optionally adhesive (page 1, second paragraph, first line; page 2, third paragraph, (I); claim 1, first two lines). Therefore, as the drug reservoir (3) shown in Figure 2 of WO '633 does not contain any adhesive, there would be no risk of adhesive creeping through the gap or incision formed between the two release papers (6).

WO '633 does not disclose "a PSA layer on the reservoir layer" (Office Action, page 7, fifth line from bottom). According to this prior art, the PSA layer is provided between the backing layer and the reservoir (see Figure 2), but not on the reservoir. This is made clear in present claim 11 by the phrase "provided with a pressure-sensitive adhesive layer".

The PSA layer, which, according to WO'633 is provided between the backing layer and the reservoir, is in contact with the reservoir, but on the "wrong side" thereof (not an application surface thereof). The peel strips (6), in the region of the overlap, do not contact or adhere to an adhesive layer.

Accordingly, the skilled person would have assumed that the two overlapping release papers show in Fig. 6 only serve the purpose of providing a gripping aid (cf. present application, page 1, last paragraph). WO '633 does not provide any hint suggesting that these overlapping release papers may have an additional function, or, in particular, that they might be useful for preventing leakage of adhesive due to cold flow, in the case where the reservoir is adhesive or contains an adhesive layer. The contrary is true: since the overlapping release papers or strips (6) do not lie directly on the surface of the layer (3), but form a free space with the reservoir layer (3) and the foil (5), it is apparent that they do not have any additional function, and at least are not able to prevent layer (3) (which according to the Examiner might be considered to be rendered pressure-sensitive adhesive on its surface) from leaking out in cold-flow. Therefore, it is our position that a man skilled in the art would not consider cited reference WO '633 and particularly Fig. 2 thereof, as a means for solving the problem which was solved according to pages 1 and 2 of the present specification.

In this connection, it was stated on page 6 (lines 4-6 from the bottom) that the "the secondary reference teaches the coverage of the adhesive layers by two overlapping sections for



protecting the contents of the device". This statement, however, does not appear to be correct, since WO '633 does not disclose overlapping sections which cover an adhesive layer, and it does not provide any explanation concerning the function of the peel strips.

In this regard, it should also be noted that WO '633 is only concerned with potential loss of active substance which may occur through the backing layer, but not to loss of active substance which may occur in the opposite direction (i.e. through the gap between the two release papers; as in the present invention).

The Examiner has pointed out that the claims are given the broadest interpretation during examination. However, even by applying broad interpretation, it is not appropriate to compare the "adhesive material/adhesive layer" (present claim 11) to the backing layer mentioned in WO '633. According to the Office Action (page 3, lines 6-10), this prior art teaches "a pressure-sensitive adhesive layer on one of the surfaces of the backing". However, instant claim 1 requires that the matrix itself is adhesive or that the matrix is provided with an adhesive layer on an application surface thereof. This is clearly different from a backing layer (which is devoid of active substance) being covered with adhesive.

Furthermore, WO '633 does not teach to position the overlap (of carrier layer) on the pressure-sensitive adhesive substrate material or layer (see instant claim 1, last part). Rather, according to this prior art document, the overlap is placed on top of non-adhesive reservoir

(reference No. 3 in Figure 2). In the configuration shown in WO '633, the overlap of the release papers (6) does not have any technical relationship with the adhesive coating (4) of the backing (2). Due to the presence of foil (5) which is located between reservoir (3) and the adhesive side (4) of the backing (2) (see WO '633, page 4 third paragraph, referring to Figure 2), the adhesive cannot pass through the foil (5). Therefore, also for this reason, the skilled person would not have assumed that the adhesive layer of the backing could leak through the foil. Accordingly, the skilled person would not have assumed the overlapping release papers could be of any benefit with respect to preventing leakage of adhesive.

For the same reason, WO '633 does not disclose a "reservoir rendered adhesive" as defined in present claim 1 (Office Action, page 7, last two lines). According to WO '633, it is the backing layer which is rendered adhesive, not the reservoir. Due to the fact that a foil (5) is placed between adhesive coating (4) of backing (2) and the reservoir (3), it is not correct to describe the reservoir as being "rendered adhesive". The reservoir of WO '633 is not rendered adhesive.

In summary, the Applicants respectfully submit that;

(a) USP '913 is not appropriate as a primary reference since it does not pertain to substrate sections whose adhesive surface is covered by a carrier layer which has an incision, and

(b) WO '633 could not have suggested the solution provided by the present invention, since it fails to address the problem of leakage of adhesive through the incision present in a carrier layer which covers the adhesive surface of an active substance-containing reservoir. It cannot be inferred from WO '633 that the overlapping peel strips might have any effect on preventing leakage of adhesive material.

For these reasons, the Applicants believe that the Examiner's conclusion according to which the presently claimed invention would have been obvious to one having ordinary skill in the art (page 4, second paragraph) is based on hindsight interpretation of the prior art, and this rejection should be withdrawn.

Claims 11-14 are now in condition for allowance

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

### **CONCLUSION**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

Application No. 09/980,211  
Amendment dated February , 2005  
Reply to Office Action of September 24, 2004

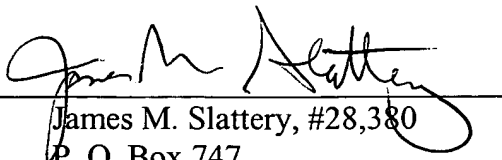
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Art Unit: 1615  
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If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 205-8000.

Pursuant to 37 C.F.R. 1.17 and 1.136(a), the Applicants respectfully petition for a two (2) month extension for time for filing a reply in connection with the present application, and the required fee of \$450.00 is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,  
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